The Sustained Aeration of Infant Lungs Study

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In this research study we compare two approaches that can be used to give breathing support to prematurely born babies. Both techniques are currently used in different countries over the world. However, at this moment we don*t know which methods is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mental impairment disorders
Study type	Interventional

Summary

ID

NL-OMON45135

Source
ToetsingOnline

Brief title
SAIL Study

Condition

- Mental impairment disorders
- Neonatal respiratory disorders

Synonym
bronchopulmonary dysplasia; chronic lung disease

Research involving
Human

Sponsors and support

Primary sponsor: National Institute of Health
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bronchupulmonary Dysplasia, Positive Pressure Ventilation, Premature infant, Sustained inflation

Outcome measures

Primary outcome

Percentage of death or bronchopulmonary dysplasia at 36 weeks gestation age.

Secondary outcome

Need for mechanical ventilation in the first 7 days of life

Need for surfactant

Neurodevelopment outcomes at 22-26 months of corrected age

Respiratory outcome at 22-26 months of corrected age

Study description

Background summary

Most prematurely born babies have difficulties with breathing and need help to take their first breaths. The medical team will provide support for the breathing and sometimes it is even necessary to place a breathing tube and to use a breathing machine (intubation and ventilation). Because the lungs of prematurely born babies are vulnerable, we try to avoid the need of intubation and ventilation. For this reason, we initially give support with a breathing mask that is placed over the mouth and nose of the baby. With his mask we give breaths.

Study objective

In this research study we compare two approaches that can be used to give breathing support to prematurely born babies. Both techniques are currently used in different countries over the world. However, at this moment we don*t know which methods is the best for prematurely born babies. We do know that premature babies who need a breathing tube are at a greater risk for developing chronic lung disease. A goal of this study is to find out which approach is most able to reduce the risk of developing chronic lung disease.

Study design

Prospective, multicenter, single blinded, randomized, controlled trial

Intervention

Sustained inflation of 15 seconds with normal pressures (20cm H2O). If the neonate doesn't respond (properly) on this, it will be given an extra sustained inflation of 15 seconds with a slightly higher pressure (25 cm H2O).

Study burden and risks

Based on their prematurity both groups have a risk on pneumothorax. Based on prior obtained research, this risk is not significantly different in both groups.

Beide groepen hebben op basis van de prematuriteit een risico op een pneumothorax. Gebaseerd op eerder verricht onderzoek is dit risico niet significant verschillend voor beide groepen.

Contacts

Public
National Institute of Health

Center Drive, Building 31, Room 2a32 31
Bethesda, MD 20892 2425
US
Scientific
National Institute of Health

Center Drive, Building 31, Room 2a32 31
Bethesda, MD 20892 2425
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants born in participating Neonatal Intensive Care Units
Gestational Age at least 23 weeks but less than 27 completed weeks
requiring resuscitation/respiratory intervention at birth

Exclusion criteria

Considered non-viable by the attending neonatologist
Refusal of antenal informed consent
Known major anomalities, pulmonary hypoplasia
Mothers who are uable to consent for their medical care and who do not have a surrogate guardian will not be approached for consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-11-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-03-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	16-06-2017
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02139800
CCMO	NL49810.058.14